Compliance Guidance

The Mammography Quality Standards Act Final Regulations Modifications to Policy Guidance Help System #1

Document issued on July 5, 2000

This document modifies and updates guidance appearing in the Policy Guidance Help System #1.

U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Mammography Standards Branch
Division of Mammography Quality and Radiation Programs
Office of Health and Industry Programs

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Charles Finder, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Charles Finder at 301-594-3332.

Additional Copies

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The Mammography Quality Standards Act Final Regulations Modifications to Policy Guidance Help System #1

Background

The Mammography Quality Standards Act was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations, under which mammography facilities are currently regulated, became effective April 28, 1999. The FDA compiled all final guidance referable to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at:

www.fda.gov/cdrh/mammography/guidance.html

This compliance guidance document serves to update the Policy Guidance Help System to be consistent with more recently issued guidance.

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the State or local authorities regarding their requirements.

Limited Attestation For Continuing Education After October 1, 1994	
~~Discussion:~~ ~~FDA will continue to accept a limited form of attestation in certain cases where the following conditions exist:~~ ~~(1) The documentation for a training event lacks specific reference that the training was in topics directly related to the regulated areas in mammography. This includes any training directly related to achieving quality mammography (e.g., anatomy of the breast, positioning, interpretation of mammographic examinations, quality assurance procedures). Training in an area not covered by the regulations shall not be accepted as meeting the requirements for initial training (e.g., stereotactic techniques, breast ultrasound, needle localization).~~ ~~(2) It is possible for conference attendees to earn training credits in different subject areas at that training event (e.g., angiography, pediatric radiography, orthopedic radiography, and mammography).~~ ~~In order to attest when these conditions apply, the interpreting physician, radiologic technologist, and medical physicist will need to provide:~~ ~~(1) A letter, certificate or other documentation from the training provider identifying the total number of credits actually earned at the conference, and~~ ~~(2) Documentation (for example, conference agendas) showing the total number of hours of training offered at the conference which were in topics directly related to the regulated areas in mammography.~~ ~~Facility personnel can then attest to the mammography training credits earned at the training event. However, the training credits attested to may not exceed the total number of credits identified in items 1 or 2 above.~~ ~~When the certificate identifies only the total number of training credits earned at the conference and it is not clear that all of the training hours were in topics directly related to the regulated areas in mammography, the inspector will~~	Discussion: FDA will continue to accept a limited form of attestation in certain cases where the following conditions exist: (1) The documentation (certificate) lacks specific reference that the education was in topics directly related to the regulated areas in mammography or the documentation does not specify the specific mammography modality(ies) credit hours included. Education directly related to achieving quality mammography (e.g., anatomy of the breast, positioning, interpretation of mammographic examinations, quality assurance procedures, stereotactic techniques, breast ultrasound, needle localization) is acceptable toward meeting the continuing education requirement. Education in an area not covered by the regulations (e.g., stereotactic techniques, breast ultrasound, needle localization) shall not be accepted toward meeting the requirements for initial training. (2) It is possible for conference attendees to earn education credits in topics not directly related to the regulated areas in mammography at that education event (e.g., angiography, pediatric radiography, orthopedic radiography) or in which more than one mammographic modality was included. In order to attest when these conditions apply, the interpreting physician, radiologic technologist, and medical physicist will need to provide: (1) A letter, certificate or other documentation from the education provider identifying the total number of credits actually earned at the conference, and (2) Documentation (for example, conference agendas) showing the total number of hours of education offered at the conference which were in topics directly related to the regulated areas in mammography and/or in a specific mammographic modality. Facility personnel can then attest to the mammography

~~need to review the conference agenda to calculate the total training credits which can be applied to the MQSA initial training requirement. The inspector must compare the number of attested hours to the total number of agenda hours that are applicable toward the initial training requirement. This ensures the attested hours do not exceed the number of applicable agenda hours.~~ ~~FDA's "Attestation Regarding Requirements of the Mammography Quality Standards Act" form (ATTESTATION FORM), or a form with similar elements or equivalent, shall be used for this purpose.~~	education and/or mammography modality specific credits earned at the education event. However, the education credits attested to may not exceed the total number of credits identified in items 1 or 2 above. In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present. FDA's "Attestation Regarding Requirements of the Mammography Quality Standards Act" form (ATTESTATION FORM), or a form with similar elements or equivalent, shall be used for this purpose.
Interpreting Physician Continuing Education (Under Personnel, Interpreting Physician) Question 15	
~~We use only one mammographic modality (screen-film) at our facility. Will I have to document six CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?~~ ~~Yes, if you are an interpreting physician or a radiologic technologist. FDA permits training in a wide variety of topics to be counted towards meeting the general 15-credit continuing education requirement. However, the regulations require that at least six of those hours be related to each modality used by an interpreting physician or radiologic technologist. If screen-film is one, or the only, modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen.~~ ~~In the case of medical physicists, the continuing education requirement is to have "hours of training appropriate to each mammographic modality evaluated" but no specific numerical value is given. The documentation must thus show that some of the 15 hours was related to screen-film mammography.~~ ~~While facilities (and their personnel) will not have to provide documentation of mammographic modality specific continuing education until June 30, 2002, at the earliest, facilities can be cited for failure to meet this requirement~~	Question: I'm an interpreting physician and use only one mammographic modality (screen-film) at my facility. Will I have to document six category I CME credits in screen-film mammography as part of the 15 general mammography CME credits? Yes. FDA permits education in a wide variety of topics to be counted towards meeting the general 15-credit continuing education requirement. However, the regulations require that at least six of those hours be related to each mammographic modality used by an interpreting physician. If screen-film is one, or the only, mammographic modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen. Personnel should have begun collecting documentation of their mammographic modality specific continuing education as of April 28, 1999. FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not break down the amount of credit issued by specific topic or mammographic modality. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting

~~after that date. Therefore, personnel should begin collecting such documentation as of 4/28/99.~~ ~~FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not breakdown the amount of credit issued by specific topic or mammographic modality. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace or another solution can be devised, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend. If needed, these agendas will allow personnel to use the limited attestation policy to document the amount of CME/CEU earned in each mammographic modality.~~	them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace, or another solution can be devised, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend in order to use the **limited attestation policy** to document the amount of CME/CEU earned in each mammographic modality. Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2004. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.
Interpreting Physician Continuing Education (Under Personnel, Interpreting Physician) Question 16	

	Question: I use Full Field Digital Mammography (FFDM) at my facility. What records should I keep with respect to the mammographic modality continuing education requirement? Answer: If you clinically use FFDM, you need to begin to collect category I CME credits in that specific mammographic modality. You will need to demonstrate that you have acquired 6 credits in digital mammography within 36 months of your first having started using FFDM. If your category I CME certificates do not identify credits by mammographic modality, personnel can use the **limited attestation policy** to satisfy the requirement. FDA is extending this policy to allow personnel with CME certificates documenting the total number of credits, but not the specific mammographic modality covered by those credits, to attest that the required amount of CME in the specific mammographic modality has been obtained. In order to use the **limited attestation policy**, personnel are reminded that they need to retain, at the facility, the certificate stating the total number of credits awarded and an agenda or syllabus showing that the number of credits in the specific mammographic modality claimed could have been earned in the course. In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present. Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2004. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.
Radiologic Technologist Continuing Education (Under Personnel, Radiologic Technologist) Question 11	
~~We use only one mammographic modality (screen-film) at our facility. Will I have to document six CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?~~	Question: I'm a radiologic technologist and use only one mammographic modality (screen-film) at my facility. Will I have to document six CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?

Old Guidance	Replaced by New Guidance
~~Yes, if you are an interpreting physician or a radiologic technologist. FDA permits training in a wide variety of topics to be counted towards meeting the general 15-credit continuing education requirement. However, the regulations require that at least six of those hours be related to each modality used by an interpreting physician or radiologic technologist. If screen-film is one, or the only, modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen.~~ ~~In the case of medical physicists, the continuing education requirement is to have "hours of training appropriate to each mammographic modality evaluated" but no specific numerical value is given. The documentation must thus show that some of the 15 hours was related to screen-film mammography.~~ ~~While facilities (and their personnel) will not have to provide documentation of mammographic modality specific continuing education until June 30, 2002, at the earliest, facilities can be cited for failure to meet this requirement after that date. Therefore, personnel should begin collecting such documentation as of 4/28/99.~~ ~~FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not breakdown the amount of credit issued by specific topic or mammographic modality. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace or another solution can be devised, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend. If needed, these agendas will allow personnel to use the limited attestation policy to document the amount of CME/CEU earned in each mammographic modality.~~	Yes. FDA permits education in a wide variety of topics to be counted towards meeting the general 15-credit continuing education requirement. However, the regulations require that at least six of those hours be related to each mammographic modality used by a radiologic technologist. If screen-film is one, or the only, mammographic modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen. Personnel should have begun collecting documentation of their mammographic modality specific continuing education as of April 28, 1999. FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not break down the amount of credit issued by specific topic or mammographic modality. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace or another solution can be devised, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend in order to use the **limited attestation policy** to document the amount of CME/CEU earned in each mammographic modality. Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2004. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.
Radiologic Technologist Continuing Education (Under Personnel, Radiologic Technologist) Question 12	

	Question: I use Full Field Digital Mammography (FFDM) at my facility. What records should I keep with respect to the mammographic modality continuing education requirement? Answer: If you clinically use FFDM, you need to begin to collect CME/CEU credits in that specific mammographic modality. You will need to demonstrate that you have acquired 6 credits in digital mammography within 36 months of your first having started using FFDM. If your CME/CEU certificates do not identify credits by mammographic modality, personnel can use the **limited attestation policy** to satisfy the requirement. FDA is extending this policy to allow personnel with CME/CEU certificates documenting the total number of credits, but not the specific mammographic modality covered by those credits, to attest that the required amount of CME/CEU in the specific mammographic modality has been obtained. In order to use the **limited attestation policy**, personnel are reminded that they need to retain, at the facility, the certificate stating the total number of credits awarded and an agenda or syllabus showing that the number of credits in the specific mammographic modality claimed could have been earned in the course. In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present. Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2004. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.
Medical Physicist Continuing Medical Education (Under Personnel, Medical Physicist) Question 10	
~~We use only one mammographic modality (screen-film) at our facility. Will I have to document six CME/CEU credits in screen-film mammography as part of the 15 general mammography CME/CEU credits?~~	Question: I'm a medical physicist and evaluate only one mammographic modality (screen-film). Will I have to document CME/CEU credits in screen-film mammography as part of the 15 general mammography

~~Yes, if you are an interpreting physician or a radiologic technologist. FDA permits training in a wide variety of topics to be counted towards meeting the general 15-credit continuing education requirement. However, the regulations require that at least six of those hours be related to each modality used by an interpreting physician or radiologic technologist. If screen-film is one, or the only, modality used, the documentation must be detailed enough to show that at least six of the 15 hours were related to film-screen.~~ ~~In the case of medical physicists, the continuing education requirement is to have "hours of training appropriate to each mammographic modality evaluated" but no specific numerical value is given. The documentation must thus show that some of the 15 hours was related to screen-film mammography.~~ ~~While facilities (and their personnel) will not have to provide documentation of mammographic modality specific continuing education until June 30, 2002, at the earliest, facilities can be cited for failure to meet this requirement after that date. Therefore, personnel should begin collecting such documentation as of 4/28/99.~~ ~~FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not breakdown the amount of credit issued by specific topic or mammographic modality. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace or another solution can be devised, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend. If needed, these agendas will allow personnel to use the limited attestation policy to document the amount of CME/CEU earned in each mammographic modality.~~	CME/CEU credits? Answer: Yes. In the case of medical physicists, the continuing education requirement is to have "hours of training appropriate to each mammographic modality evaluated" but no specific numerical value is given. Your documentation must therefore show that some of the 15 hours were related to screen-film mammography. Personnel should have begun collecting documentation of their mammographic modality specific continuing education as of April 28, 1999. FDA recognizes that most of the documentation currently being issued by continuing medical education entities does not break down the amount of credit issued by specific topic or mammographic modality. Therefore, FDA is taking a dual approach to dealing with this problem. First, discussions are being held with appropriate CME/CEU granting organizations requesting them to identify, on their certificates, the amount of mammographic modality specific education. Second, until these certificates become commonplace or another solution can be devised, we strongly recommend that personnel keep the agendas (or similar documents) of the courses or other educational activities they attend in order to use the **limited attestation policy** to document the amount of CME/CEU earned in each mammographic modality. Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2004. This will allow CME/CEU providers more time to provide mammographic modality specific documentation to their students.

Medical Physicist Continuing Medical Education (Under Personnel, Medical Physicist) Question 11	
	Question: I evaluate Full Field Digital Mammography (FFDM) units. What records should I keep with respect to the mammographic modality continuing education requirement? Answer: If you evaluate FFDM, you need to begin to collect CME/CEU credits in that specific mammographic modality. You will need to demonstrate that you have acquired some credits in digital mammography within 36 months of your first having started using FFDM. If your CME/CEU certificates do not identify credits by mammographic modality, personnel can use the **limited attestation policy** to satisfy the requirement. FDA is extending this policy to allow personnel with CME/CEU certificates documenting the total number of credits, but not the specific mammographic modality covered by those credits, to attest that the required amount of CME/CEU in the specific mammographic modality has been obtained. In order to use the **limited attestation policy**, personnel are reminded that they need to retain, at the facility, the certificate stating the total number of credits awarded and an agenda or syllabus showing that the number of credits in the specific mammographic modality claimed could have been earned in the course. In most cases, the inspector will only look for the certificate and the attestation form. However, the inspector may make spot checks to verify that an agenda or syllabus is present. Note: Inspectors will not cite facilities for the mammography modality specific continuing education requirement before April 28, 2004. This will allow CME/CEU providers more time to provide adequate documentation to their students.
Phantom Images Exposed in a Fully Automatic Mode, if that is the Clinically-used Technique (Under Inspection, X-ray)	
~~Discussion:~~ ~~Many mammographic x-ray systems have more than one automatic mode of operation. The most conventional mode of automatic requires that the technologist set a specific~~	Discussion: Many mammographic x-ray systems have more than one automatic mode of operation. The most common automatic mode requires that the technologist set a

~~kVp value and the mAs for the exposure is automatically controlled by the system (referred to on the 3.5.2 Exposure/Beam Quality (HVL) screen as the "Auto mode). The technologist can vary the exposure in this mode by setting the kVp, adjusting the density control feature, or both. A more advanced mode is where the system automatically controls the kVp and the mAs (referred to on the 3.5.2 Exposure/Beam Quality (HVL) screen as the "Auto Full" mode). In this latter mode, the technologist can only adjust the exposure by the density control. The actual names for the different modes of operation will vary with the different models of systems in facilities.~~	specific kVp value with the unit automatically determining the mAs for the exposure. This type of operation is commonly called the AEC, Auto-mAs, or Auto-timed mode. The technologist can vary the exposure in this mode by setting the kVp, adjusting the density control setting, or both. A more advanced mode is where the system automatically controls the kVp and the mAs (commonly called the Full-Auto mode). In this latter mode, the technologist can only adjust the exposure by use of the density control. The actual names for the different modes of operation will vary with the different make and model of the x-ray system.
~~For equipment testing involving the phantom, inspectors should use the same technique factors and mode of operation that the facility uses for patients. When a facility uses the "Auto Full" type mode for patients whose physical characteristics are represented by the phantom,* the inspector should make an exposure with the phantom to determine what kVp is selected by the x-ray system. This same kVp should be selected when the beam quality testing is conducted in the manual mode of operation. In the event that the displayed kVp after the exposure with the phantom has a three-digit display (e.g., 25.7 kVp), but the manual mode only allows selection of two digits (e.g., 25 kVp), round up or down based on the final digit (example: for 25.1 to 25.4, use 25 kVp; for 25.5 to 25.9, use 26.0 kVp).~~	For equipment testing involving the phantom, inspectors should use the same technique factors and mode of operation that the facility uses for its patients with the standard breast (compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition). When a facility typically uses the Full-Auto mode for its clinical examinations, the inspector should make an exposure of the phantom using the Full-Auto mode and record the kVp selected by the x-ray system. This same kVp should be used when the beam quality (HVL) testing is conducted in the manual mode of operation. In the event that the displayed kVp after the exposure with the phantom has a three-digit display (e.g., 25.7 kVp), but the manual mode only allows selection of two digits (e.g., 25 kVp), round up or down based on the final digit (example: for 25.1 to 25.4, use 25 kVp; for 25.5 to 25.9, use 26.0 kVp).
~~Note about facility phantom QC: If the facility uses the "Auto Full" type mode for patients, but uses the "Auto mode for the phantom, advise them that they should use the modes of operation, technique factors, and density settings for the phantom test as they would for patients whose physical characteristics are represented by the phantom.*~~	Note about facility phantom QC: If the facility typically uses the Full-Auto mode for its clinical examinations, it must use this same mode for its weekly phantom QC test.
~~* The phantom represents a patient with a compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue and 50% glandular tissue in composition.~~	

Facility Use of a Cracked Breast Phantom (Under Inspection, Quality Control and Quality Assurance)	
~~Issue:~~ ~~It has come to FDA's attention that some facilities are using cracked or broken phantoms for performing the weekly Phantom Image Quality Control (QC) test, while having used a borrowed phantom to get through the accreditation process. This practice raised the following issue.~~ ~~Should this practice be allowed and, if not, what should inspectors do when encountering such a situation? It is assumed that the crack or break is visible on the image.~~ ~~Discussion:~~ ~~Crack(s) in the breast phantom which a facility uses to perform their weekly Phantom Image QC test may affect the validity of the phantom QC test results. The use of a cracked or broken phantom is clearly not consistent with performing QC testing properly. However, the inspection procedures do not have a particular item or question which relates directly to facility use of a cracked or broken phantom for their QC testing. Therefore, FDA requests all inspectors to incorporate the following policy into their MQSA inspections.~~ ~~Policy:~~ ~~When a facility is using a cracked or broken breast phantom for their Phantom Image QC testing, the inspection question "C/A documented?", which is located on the 3.9.2 Phantom Image QC screen of the inspection software, should be answered "No" (since the use of such a phantom clearly constitutes an uncorrected problem) and an explanation placed in the printed Remarks section for this screen. The facility should be advised to acquire a new phantom.~~ ~~Note: If the facility is using an older version of the ACR-approved phantom, they should contact the vendor where it was purchased to order a replacement with a current phantom.~~	Issue: It has come to FDA's attention that some facilities are using cracked or broken phantoms for performing the weekly Phantom Image Quality Control (QC) test, while using a borrowed phantom to get through the accreditation process. This practice raised the following issue. Should this practice be allowed and, if not, what should inspectors do when encountering such a situation? It is assumed that the crack or break is visible on the image and interferes with the scoring of the phantom (simulates masses, fibers or specks, and/or obscures one or more of the test objects). Discussion: Crack(s) in the breast phantom which a facility uses to perform their weekly Phantom Image QC test may affect the validity of the phantom QC test results. The use of a cracked or broken phantom that interferes with the scoring of the phantom image is clearly not consistent with performing QC testing properly. However, the inspection procedures do not have a particular item or question which relates directly to facility use of a cracked or broken phantom for their QC testing. Therefore, FDA requests all inspectors to incorporate the following policy into their MQSA inspections. Policy: When a facility is using a cracked or broken breast phantom that interferes with the scoring of the phantom image for their Phantom Image QC testing, the inspection question "C/A documented?", which is located on the 3.9.2 Phantom Image QC screen of the inspection software, should be answered "No" (since the use of such a phantom constitutes an uncorrected problem) and an explanation of the citation should be placed in the printable Remarks section for this screen. The facility should be advised to acquire a new phantom.

	Note: If the facility is using an older version of the ACR-approved phantom, they should contact the vendor where it was purchased to replace it with a current phantom.
Responsible Individuals For Quality Assurance Program (Under Quality Assurance, General) Question 1	
~~What criteria will FDA use to determine that facilities meet the MQSA requirements for assigning responsibilities to quality assurance personnel?~~ ~~Facilities must provide the following documentation:~~ ~~1. The names of the lead-interpreting physician, medical physicist(s), quality control technologist(s), reviewing interpreting physician(s) and any other facility personnel with delegated quality assurance responsibilities.~~ ~~2. A statement of their respective responsibilities.~~	Question 1:What criteria will FDA use to determine that facilities meet the MQSA requirements for assigning responsibilities to quality assurance personnel? Answer: Facilities must provide the following documentation: 1. The names of the lead-interpreting physician, medical physicist(s), quality control technologist(s), audit interpreting physician(s) and any other facility personnel with delegated quality assurance responsibilities. 2. A statement of responsibilities. Because the regulations already specify the responsibilities of the lead-interpreting physician, medical physicist(s), quality control technologist(s), and audit interpreting physician(s), the facility does not have to restate the responsibilities of these individuals. However, if the facility delegates quality assurance responsibilities to someone other than the lead-interpreting physician, medical physicist(s), quality control technologist(s), or audit interpreting physician(s), a statement of responsibilities for that individual(s) has to be provided.
Governmental Entity	
~~A facility will have 30 days to respond to this mailing to declare themselves as qualifying as a Government entity. FDA will review each declaration to determine if a facility qualifies as a Government entity.~~ ~~If FDA disallows a facility's claim or if a facility does not respond to the Government entity form, a bill will be sent with payment due in 30 days. FDA will give facilities a second opportunity to claim status as a government entity, if applicable, by including this form in the billing mailing.~~	<u>Governmental Entity</u> Discussion: A governmental entity is a mammography facility that meets either of the following criteria: 1. The facility is operated by any federal department, state, district, territory, possession, federally-recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof. or 2. The facility provides services under the Breast and

	Cervical Cancer Mortality Prevention Act of 1990, and at least 50% of the mammography screening examinations provided during the preceding 12 months were funded under the statute. A Governmental Entity Declaration, FDA Form 3422, is included with each invoice for MQSA inspection services. A facility that believes that it qualifies as a governmental entity must complete this Declaration, have it signed by the facility's Chief Financial Officer or Chief Operating Officer (or equivalent responsible person), and return it to FDA.
Governmental Entity Declaration Forms	
	Governmental Entity Declaration Forms Discussion: A Governmental Entity Declaration, FDA Form 3422, is included with each invoice for MQSA inspection services. A facility that believes that it qualifies as a governmental entity must complete this Declaration, have it signed by the facility's Chief Financial Officer or Chief Operating Officer (or equivalent responsible person), and return it to: MQSA Government Entity Declaration FDA Mammography Quality Assurance Program P.O. Box 6057 Columbia, MD 21045-6057 FDA will review each declaration to determine if a facility qualifies as a Governmental entity.
Inspections of Certified Facilities Currently Not Performing Mammography (Under Inspections, General) Question 1	

~~Should a certified facility which is not currently performing mammography be inspected?~~ ~~Yes. In keeping with the intent of the regulations, once a facility is certified, that facility must maintain its certified status by:~~ ~~· having an annual physics survey performed,~~ ~~· undergoing periodic audits and reviews by their accreditation body,~~ ~~· permitting an annual MQSA inspection,~~ ~~· paying an inspection fee, and~~ ~~· correcting any deficiencies found during inspections.~~ ~~Should a certified facility choose not to participate in these requirements, it must relinquish its certified status. This means the facility must notify its accreditation body and the FDA* and mail its certificate to FDA** as soon as possible. Once the facility's certified status has been relinquished, it cannot lawfully perform mammography.~~ ~~* FDA MQSA Facility Hotline Number: 1(800) 838-7715~~ ~~** FDA – MQSA~~ ~~P.O. Box 6057~~ ~~Columbia, MD 21045-6057~~ ~~Should the facility decide to perform mammography services in the future, it must proceed through the accreditation process again.~~	Question 1: Should a certified facility that is not currently performing mammography be inspected? Answer: Yes. In keeping with the intent of the regulations, once a facility is certified, that facility must maintain its certified status by: · having an annual physics survey performed, · undergoing periodic audits and reviews by their accreditation body, · permitting an annual MQSA inspection, · paying an inspection fee, and · correcting any deficiencies found during inspections. Should a certified facility choose not to meet these requirements, it must relinquish its certified status. This means the facility must notify its accreditation body and the FDA (Facility Hotline Number: (800) 838-7715, Address: FDA – MQSA, P.O. Box 6057, Columbia, MD 21045-6057) as soon as possible. Once the facility's certified status has been relinquished, it cannot display the MQSA certificate and cannot lawfully perform mammography. Should the facility decide to perform mammography services in the future, it must proceed through the accreditation process again.
Facilities That Have Closed But Are Still Certified (Under Inspection, General)	
	Discussion: Occasionally, inspectors, State programs, and FDA field offices inform the division about facilities that are listed as certified but who are no longer performing mammography. As you know, a facility's accreditation remains valid until it expires. Thus, the American College of Radiology (ACR) requires a facility that is in the process of closing to notify them so that the ACR can withdraw that facility's accreditation. In situations where such a facility did not contact the ACR about its new status, the ACR will continue to list it as accredited

	and subsequently certified. The ACR has a standard operating procedure whereby they try to verify via a letter or telephone call the status of a facility when they learn of its change in status. Upon validating a facility's closure, the ACR updates its records to indicate accreditation withdrawal for the facility in question and notifies FDA of that facility's new status. The State accreditation bodies also have methods for verifying the status of a facility, although their approaches differ from the arrangement between the FDA and ACR because their inspection and accreditation programs communicate more directly. If you learn of a facility that is closing or has closed, please contact the MQSA Inspector Helpdesk via electronic mail. If you have any letters or other documents confirming the closure, please fax them to us. Upon receiving this information, DMQRP will work with the ACR and the State Accreditation Bodies to verify whether a facility is no longer performing mammography. DMQRP will then delete the facility's certification once their accreditation body has updated their database.
Reestablishing Processor Operating Levels Over the 5-Day Period (Under Inspection, Quality Control and Quality Assurance) Question 1	
~~Under what situations are facilities allowed to correct or re-establish processor operating levels? Can a facility continue to process films when establishing or re-establishing operating levels over the 5-day period?~~ ~~Facilities should re-establish processor operating levels when:~~ ~~1. There is a change in mammography film, a change in film brand/type, or a change in emulsion numbers (crossover)~~ ~~2. When there is a change in processing cycles - Standard to extended/extended to standard~~ ~~A facility may process films while establishing or re-establishing operating levels over the 5-day period.~~	Question 1: In which situations should facilities establish new processor operating levels? Answer: The most warranted and common situations for a facility to establish new processor operating levels are when processor QC testing is initiated for a new processor or when a significant change is made in the processing system. Some significant changes that may necessitate the establishment of new operating levels include: change in film brand/type, change in chemical brand/type, change in replenishment rates, change in specific gravity automixer settings, change of sensitometer or densitometer, or a change in processing conditions (standard vs. extended). Replacement of chemistry (same brand/type) as part of routine preventative maintenance should not necessitate establishment of new operating levels.

~~However, a facility must not process films while their processor is out-of-limits. The problem must be identified and corrected before processing can continue.~~	Facilities should not use the establishment of new operating levels to correct problems in the processing system, but should troubleshoot and solve the problem with appropriate corrective action. FDA recommends that the facility consult with their medical physicist prior to establishing new operating levels. Question 2: During the time a facility is establishing new operating levels (typically done by performing a five-day data plot average): A) does the facility continue to plot the data on the processor chart? B) Is the facility exempt from having to stay within the old processor action limits during the five-day averaging period? Answer: While establishing new operating levels (during which time the facility can continue to process mammograms), the facility must continue to perform the daily processor QC tests and should plot the data in the same manner it usually does. This may be done on the same graph as the previous data or on a different graph. In either event, this new data should be clearly identified as being derived during the establishment of the new operating levels, so that both the facility and the inspector are aware of the origins of this data. Because no operating level has yet been established, the facility is exempt from having to stay within any processor action limits during this five-day averaging period. FDA recommends that during the five-day averaging period, the facility daily perform and evaluate a phantom image as a means of monitoring image quality.
Additional Mammography Review and Patient Notification (Under Additional Mammography Review and Patient Notification) Question #5	
~~Question 5: Where can a facility obtain more information about additional mammography review and patient notification? FDA is developing further guidance regarding additional mammography review and patient notification. This document will be posted on the FDA CDRH website in the near future, and will be available upon request from the FDA. FDA will publish a Notice of Availability in the~~	Delete Question and Answer.

~~Federal Register and in Mammography Matters when the guidance is available.~~	